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| 10/667,848 | 09/22/2003 | Edward F. Ikeguchi | MS1-203-US | 1385 |

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| EXAMINER | |
|---|---|
| RAJ, RAJIV J | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/667,848 | IKEGUCHI ET AL. | |
| | Examiner | Art Unit | |
| | RAJIV J. RAJ | 3686 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16 January 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

1. This action is in reply to the amendment filed on 08 April 2009.
2. Claims 1-3 & 5-18 have been amended.
3. Claims 1-3, 5-20, & 22-24 are currently pending and have been examined.

### *Information Disclosure Statement*

4. The Information Disclosure Statement filed 16 January 2009 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-20 & 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has added claim language "*without compromising*" into independent claims 1, 12 and 18. Support for this claim language is not found in Applicant's specification. "*without compromising*" claims a

broader interpretation than that found in applicant's specification (see at least Applicant's Specification [0068])

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 5-20 & 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is vague and indefinite how the data is "not compromised". Examiner points out, based on applicant's claim language, *"without compromising the integrity of the ongoing blinded clinical trial"*, can be accomplished by not publishing the data of the "*ongoing blinded clinical trial*" to the patient, user, clinicians, etc. For the purposes of this examination the claim language will be interpreted as cited in the prior art.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. The previous 35 U.S.C. 101 rejection of claims 1-3 & 5-17 have been withdrawn in light of applicant's amendments.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-3, 5-20, & 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (US 2002/0099302) (hereinafter Bardy) in view of Pence et al. (US 5978751) (hereinafter Pence) in view of Applicant's Own Admission (AOA).

**Claim 1**

**Bardy as shown, discloses the following limitations:**

- *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])
- *performing a statistical analysis on the accessed trial database*; (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)

- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059])
- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035], [0037] Fig:2-4 Items:40-73, 80-91, 95-111 & related text)
- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035], [0043-44], Fig.5 Items:26,27,125,129-133 & related text)
- *storing the result of the statistical analysis in a memory device;* (see at least Bardy Claims:22,24,25,27,29 & 30)

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *repeating said computer-executable instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing without compromising the integrity of the ongoing blinded clinical trial if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50-54 & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and

systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Bardy/Pence does not disclose the following limitations, however AOA, as shown, does:

- *without suspending the ongoing blinded clinical trial;* (see at least AOA [0006-0010])
- *without compromising the integrity of the ongoing blinded clinical trial;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50-54 & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the features of AOA into Bardy/Pence. One of ordinary skill in the art would have added these features into Bardy/Pence with the motivation to provide an improved invention for analyzing and managing clinical data while maintaining the reliability and veracity of the collected data.

**Claim 2**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis*; (see at least Bardy [0048])
- *retrieving only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

**Claim 3**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *computer-executable instruction for waiting for a predetermined time period prior to the repeating said computer-executable instruction for accessing a trial database, performing and determining while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value;* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

**Claim 5**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Pence further discloses the following limitation:

- *computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would

have added this feature into Bardy/Pence with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure that the integrity of the database is maintained.

**Claim 6**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *computer-executable instruction for performing a statistical analysis is executed without locking the trial database* (see at least Bardy [0048])

**Claim 7**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *reading a predefined criteria that defines the level of cleanliness of trial data required for analysis*; (see at least Bardy [0048])
- *retrieving only those trial data that meet the predefined criteria from the trial database*; (see at least Bardy [0011])

**Claim 8**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 7. Bardy further discloses the following limitation:

- *ongoing blinded clinical trial;* (see at least Bardy [0008])

Bardy does not disclose the following limitations, however Pence, as shown, does:

- *computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user to preserve the blindness of the clinical trial;* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence/AOA. One of ordinary skill in the art would have added this feature into Bardy/Pence/AOA with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

**Claim 9**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 1. Bardy further discloses the following limitation:

- *computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value*. (see at least Bardy Fig. 5 Item:127 and [0041])

**Claim 10**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 9. Pence further discloses the following limitation:

- *wherein the predetermined threshold value includes a predetermined statistical significance value* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence/AOA. One of ordinary skill in the art would have added this feature into Bardy/Pence/AOA with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

**Claim 11**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 10. Pence further discloses the following limitation:

- *retrieving a user defined statistical model; and running the retrieved user defined statistical model on the trial database.* (see at least Pence Column:7 Lines:28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence/AOA. One of ordinary skill in the art

would have added this feature into Bardy/Pence/AOA with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

**Claim 12**

Bardy as shown, discloses the following limitations:

- *accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;* (see at least Bardy [0008] & [0009])
- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial*; (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)
- *accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;* (see at least Bardy [0037])
- *producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;* (see at least Bardy Fig.5 Items:26,27,125,129-133)
- *determining whether the result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059])
- *storing the result of the statistical analysis in a memory device;* (see at least Bardy Claims:22,24,25,27,29 & 30)

Bardy does not disclose the following limitation, however Pence, as shown does:

- *repeating said computer-executable instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing without compromising the integrity of the ongoing blinded clinical trial if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50-54 & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Bardy/Pence does not disclose the following limitations, however AOA, as shown, does:

- *without suspending the ongoing blinded clinical trial;* (see at least AOA [0006-0010])
- *without compromising the integrity of the ongoing blinded clinical trial;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50-54 & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the features of AOA into Bardy/Pence. One of ordinary skill in the art would have added these features into Bardy/Pence with the motivation to provide an improved invention for analyzing and managing clinical data while maintaining the reliability and veracity of the collected data.

**Claim 13**

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; and(see at least Bardy [0048])
- *retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.* (see at least Bardy [0011] )

**Claim 14**

The combination of Bardy/Pence discloses all the limitations of Claim 12. Pence further discloses the following limitations:

- *computer-executable instruction for storing the produced grouped database in a memory device that is inaccessible by any user* (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

**Claim 15**

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *computer-executable instruction for performing a statistical analysis is executed without locking the trial database.* (see at least Bardy [0048])

**Claim 16**

The combination of Bardy/Pence discloses all the limitations of Claim 12. Bardy further discloses the following limitations:

- *computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.* (see at least Bardy Fig. 5 Item:127 and [0041])

**Claim 17**

The combination of Bardy/Pence discloses all the limitations of Claim 16. Pence further discloses the following limitations:

- *wherein the predetermined threshold value includes a predetermined statistical significance value.* (see at least Pence Column:7 Lines28-31)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

**Claim 18**

Bardy as shown, discloses the following limitations:

- *a storage device operable to store a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study*; (see at least Bardy [0035])
- *a processor coupled to the storage device*; (see at least Bardy Fig. 1 Items14,16-18)
- *an analysis program executable by the processor* (see at least Bardy Fig. 5 Items16,131)
- *access the trial database to retrieve the trial data;* (see at least Bardy [0037] & [0043])
- *accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;* (see at least Bardy [0011], [0035] & [0037])
- *generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;* (see at least Bardy [0033], [0035] Fig.5 Items:26,27,125,129-133 & related text)
- *performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial*; (see at least Bardy [0009], [0037], Fig:5 Items:16, 125-134 & related text)
- *determine whether the output result of the statistical analysis exceeds a predetermined threshold value*; (see at least Bardy [0059])

Bardy does not disclose the following limitation, however Pence, as shown does:

- *repeat the statistical analysis while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the*

*predetermined threshold value* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50, 52 "Detail 'A'" & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy. One of ordinary skill in the art would have added this feature into Bardy with the motivation of providing a more efficient and systematic approach to detecting trends in continuously collected data indicative of the progression or regression from the user defined threshold value, using an automated method and system.

Bardy/Pence does not disclose the following limitations, however AOA, as shown, does:

- *without suspending the ongoing blinded clinical trial;* (see at least AOA [0006-0010])
- *without compromising the integrity of the ongoing blinded clinical trial;* (see at least Pence Column:5 Lines:30-46, Fig. 2 Items:50-54 & related text)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the features of AOA into Bardy/Pence. One of ordinary skill in the art would have added these features into Bardy/Pence with the motivation to provide an improved invention for analyzing and managing clinical data while maintaining the reliability and veracity of the collected data.

**Claim 19**

The combination of Bardy/Pence/AOA discloses all the limitations of Claim 18. Bardy further discloses the following limitations:

- *read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis*; (see at least Bardy [0048])
- *retrieve only those trial data that meet the user defined criteria from the trial database* (see at least Bardy [0011])

**Claim 20**

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitations:

- *wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.* (see at least Pence Fig. 2 Items:50,51,52 & "Detail 'A'")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

**Claim 22**

The combination of Bardy/Pence discloses all the limitations of Claim 18. Pence further discloses the following limitation:

- *a memory device coupled to the processor* (see at least Pence Fig. 1 Items:11,15 and related text).

- *being inaccessible to any user, wherein the grouped database is stored only in the memory device*. (see at least Pence Column:5 Lines:47-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the feature of Pence into Bardy/Pence. One of ordinary skill in the art would have added this feature into Bardy/Pence with the motivation to provide a more efficient approach for continuously monitoring clinical trial data, for accurately determining when the user defined threshold value is exceeded. (see at least Pence Column:2 Lines:23-27)

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to further restrict access to the database for all users, in order to ensure the integrity of the database is maintained.

**Claim 23**

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program performs the statistical analysis without locking the trial database* (see at least Bardy [0048])

**Claim 24**

The combination of Bardy/Pence discloses all the limitations of Claim 18. Bardy further discloses the following limitation:

- *wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value* (see at least Bardy [0059])

***Response to Arguments***

14. Applicant's arguments received on 08 April 2009 have been fully considered but they are not persuasive. Applicants' arguments will be addressed herein below in the order in which they appear in the response filed 08 April 2009.

15. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

16. In response to applicant's argument that Bardy & Pence are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

17. In response to applicant's argument that the prior Office Action fails to teach "*without compromising the integrity of the ongoing blinded clinical trial*", Examiner points out that this claim language has been added and is addressed in this Office Action.

18. In response to applicant's argument that the prior Office Action fails to "teach or suggest a method and system of continuously analyzing trial data of an ongoing blinded clinical trial utilizing multi-arm study without suspending compromising the integrity of the ongoing clinical trial", Examiner respectfully disagrees, pointing out that this assertion is based on the applicant's opinion and Examiner asserts that the cited prior art does disclose applicant's claim language.
19. Applicant appears to argue that the prior art fails to teach *blinded clinical trials*. However, Examiner reasserts that this aspect of the limitations fails to make the invention patentable, as this concept is already known in the art. (see at least Applicant's Own Admission [0002-0050]) Further, Applicant's claim language: *blinded clinical trials;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Bardy/Pence. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a substantial difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, then it meets the claim.
20. Examiner notes that applicant's subsequent arguments repeat substantially similar arguments to those above, and thus will be addressed in the same manner as above.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAJIV J. RAJ whose telephone number is (571) 270-3930. The examiner can normally be reached on Monday thru Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/RJR/
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